

## Nixi Laboratories Pvt. Ltd.

VPO: MouzaOgli, Sadhora Road, Kala Amb Distt. Sirmour (H.P.)

| Product Name CERTIFICATE OF ANALYSIS FINISHED PRODUCTS |                                |               |                   |  |
|--|--------------------------------|---------------|-------------------|--|
| Product Name   | Artecan                        | AR. No.       |                   |  |
| Generic Name   | Artesunate Injection IP 120 mg | A11. 110.     | NL/DI/FG/24/404   |  |
| Mother Batch No.                                       | D24AE006                       | Reference     | TD.               |  |
| Child Batch No.  | D24AE006B                      | Batch Size    | IP<br>10200 Vials |  |
| Mfg. Date  | 04/2024                        | Exp. Date     |                   |  |
| Specification No.                                      | OC/DDIM CIGARIA                | Standard Test | 03/2026           |  |
| (STS No)   | QC/DPI/FG/STS/002-02           | Procedure No. | QC/DPI/FG/STP/002 |  |
| Sample Quantity  | 60Vials                        | Sample Date   |                   |  |
| Release Date   | 13/06/2024                     |               | 30/05/2024        |  |

| Sr. No.   | Test                            | Specification                             | Observat*                          |
|-----------|---------------------------------|---|------------------------------------|
| 1.        | Description                     | White or almost white crystalline         | Observation                        |
|           | •                               | powder filled in clear glass vial,        | White crystalline powder filled i  |
|           |                                 | plugged with rubber stopper and           | clear glass vial, plugged with gre |
|           |                                 | sealed with flip off aluminum seal.       | rubber stopper and sealed with     |
| 2.        | Identifications Tost A          | 1   | flip off aluminum seal.            |
| <b>4.</b> | omitted if test A is carried of | be omitted if test B, C and D are carried | d out. Test B, C and D may be      |
|           | omitted it test A is carried (  | out.                                      |                                    |
| \$ ·      | A Des Toric                     |   |                                    |
|           | A. By Infrared                  | Compare the spectrum with that            | Complies                           |
|           | Absorption Spectroscopy         | obtained with Artesunate WS or            |                                    |
|           | (IR)                            | with the reference spectrum of            |                                    |
|           |                                 | Artesunate.                               |                                    |
|           |                                 |   |                                    |
|           | B. By Thin-layer                | Any secondary spot in the                 | Complies                           |
|           | Chromatography (TLC)            | chromatogram obtained with the test       |                                    |
|           | om omatography (TLC)            | solution is not more intense than the     |                                    |
|           |                                 |   |                                    |
|           |                                 | spot in the chromatogram obtained         |                                    |
|           |                                 | with the reference solution.              | •                                  |
|           | C. By Chemical                  | A light mod winter 1                      |                                    |
|           |                                 | A light red violet colour is produced.    | Complies                           |
|           | D. By Chemical                  |   |                                    |
|           |                                 | A reddish-brown colour is produced.       | Complies                           |
| 3.        | Clarity of solution             | The solid dissolve completely,            | Complies                           |
|           | ·                               | leaving no visible residue as             | o omprior                          |
|           |                                 | undissolved matter.                       |                                    |
|           |                                 |   | C 1.                               |
|           |                                 | The constituted injection is not          | Complies                           |
|           |                                 | significantly less clear than an equal    | র                                  |
|           |                                 | volume of the diluent or of water for     |                                    |
|           |                                 | injections contained in a similar         |                                    |
|           | ANAL VSED DV                    |   |                                    |

|                 | ANALYSED BY   | CHECKED BY     | APPROVED BY  |
|-----------------|---------------|----------------|--|
| Name            | Akhlak        | Ganesh Jaiswal |  |
| Signature       | 1110016       | San (3 0) (8)  | Aditya Singh   |
| Date            | 13/06/14      | 131. 6/2M      | o de la companya della companya della companya de la companya della companya dell |
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Sample Quantity

Release Date

60Vials

13/06/2024

## Nixi Laboratories Pvt. Ltd. VPO: MouzaOgli, Sadhora Road, Kala Amb Distt. Sirmour (H.P.)

Sample Date

30/05/2024

| •                 | CERTIFICATE OF AN              | NALYSIS FINISHED PR | PODUCTS           |
|-------------------|--------------------------------|---------------------|-------------------|
| Product Name      | Artecan                        | AR. No.             | NL/DI/FG/24/404   |
| Generic Name      | Artesunate Injection IP 120 mg | 1220 1101           | NE/DI/10/24/404   |
| Mother Batch No.  | D24AE006                       | Reference *         | TP .              |
| Child Batch No.   | D24AE006B                      | Batch Size          | 10200 Vials       |
| Mfg. Date         | 04/2024                        | Exp. Date           |                   |
| Specification No. |                                | Standard Test       | 03/2026           |
| (STS No)          | QC/DPI/FG/STS/002-02           | Procedure No.       | QC/DPI/FG/STP/002 |
| Cample O          | COXY: 1                        | Troccuure 140.      |                   |

|     |  | <u> </u>                                   | 8                          |
|-----|--|--|----------------------------|
|     |  | container and examined in the same manner. |                            |
| 4.  | Average filled Weight  | $128 \text{ mg} \pm 5\%$                   | 127.6 mg                   |
| 5.  | Uniformity of filled<br>Weight                               | Average filled weight ± 5%                 | -2.23 to +1.14 %           |
| 6.  | Particulate matter   |  |                            |
|     | Visible particles  | Should be free from visible particles      | Complies                   |
|     | For sub visible particles: (i) Equal to or greater than 10µm | NMT 6000particles/container                | 2174.0 particles/container |
|     | (ii) Equal to or greater than 25µm                           | NMT 600particles/container                 | 5.3 particles/container    |
| 7.  | Sterility  | Should comply the test of sterility        | Complies                   |
| 8.  | Bacterial Endotoxins   | NMT 2.5 EU /mg of Artesunate.              | Complies                   |
| 9.  | Water Content  | NMT 0.5%                                   | 0.31 %                     |
| 10. | Related substances   |  |                            |
|     | (i) Impurity A   | Not more than 1.0%                         | Not Detected               |
|     | (ii) Impurity B  | Not more than 0.5%                         | Not Detected               |
|     | (iii) Impurity C   | Not more than 0.3%                         | 0.10%                      |
|     | (iv) Any other secondary<br>Imp                              | Not more than 0.3%                         | Not Detected               |
|     | (v) Sum of all impurities                                    | Not more than 2.0%                         | Not Detected               |
| 11. | Assay:<br>Each Vial Contains:                                |  |                            |
|     | Artesunate (Sterile) IP 120 mg                               | 108.0 mg to 132.0 mg (90.0 % to 110.0 %)   | 126.90 mg<br>(105.75 %)    |

|               | ANALYSED BY     | CHECKED BY          | APPROVED BY  |
|---------------|-----------------|---------------------|--------------|
| Name          | Akhlak          | Ganesh Jaiswal      | Aditya Singh |
| Signature     | LALLOWIN        | au 61 yaw (abora or |              |
| Date          | 18/00/          | 131 / ST QC         | A POP M      |
| Format No.:SO | P/OC/013/F03-03 | - INADDRO           | 121 (7)      |

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## Nixi Laboratories Pvt. Ltd. VPO: MouzaOgli, Sadhora Road, Kala Amb Distt. Sirmour (H.P.)

| Product Name Actions Actions CERTIFICATE OF ANALYSIS FINISHED PRODUCTS |                                |                             |                   |  |
|--|--------------------------------|-----------------------------|-------------------|--|
| Product Name   | Artecan                        | AR. No.                     |                   |  |
| Generic Name   | Artesunate Injection IP 120 mg | AK. 140.                    | NL/DI/FG/24/404   |  |
| Mother Batch No.   | D24AE006                       | Defe                        | , .               |  |
| Child Batch No.  | D24AE006B                      | Reference                   | IP                |  |
| Mfg. Date  | 04/2024                        | Batch Size                  | 10200 Vials       |  |
| Specification No.  | 04/2024                        | Exp. Date                   | 03/2026           |  |
| (STS No)   | QC/DPI/FG/STS/002-02           | Standard Test Procedure No. | QC/DPI/FG/STP/002 |  |
| Sample Quantity  | 60Vials                        | Sample Date                 | 30/05/2024        |  |
| Release Date   | 13/06/2024                     | 1                           | 30/03/2024        |  |

RESULT: The above sample COMPLIES/DOES NOT COMPLY as per Specification No-QC/DPI/FG/STS/002-02.

Conclusion: In the opinion of the under signed the sample referred above is of STANDARD QUALITY / IS NOT STANDARD QUALITY as defined in the Drugs & Cosmetics Act, 1940 and the rules made hereunder

|                 |               |   | <b>,</b>   |
|-----------------|---------------|---|--|
|                 | ANALYSED BY   | CHECKED BY                              | APPROVED BY  |
| Name            | Akhlak        | Ganesh Jaiswal                          |  |
| Signature       | 1.1016        | and | Aditya Singh   |
| Date            | 13/06/14      | 13/06/2000                              | The state of the s |
| Format No.:SOP/ | QC/013/F03-03 | LAPPRO (APPRO                           | MEDIM 1001   |

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